Return to life, return to work Clinical Research Grants Application Guide

1. Introduction

This Application Guide serves to outline the overarching funding rules of the 'Return to life, return to work' Clinical Research Grants facilitated by the Stroke Foundation. This document should be read before completing an application form.

2. Targeted Clinical Research

Supported by the Australian Government's Medical Research Future Fund (MRFF), the Stroke Foundation will facilitate a targeted clinical research investment in stroke recovery for young survivors through two dedicated research grants funded from 2019-2021:

- **Clinical Trial: Perispinal Etanercept (PSE) as a therapy promoting recovery after chronic stroke for younger stroke survivors in Australia (particularly those of working age)**
- **Clinical Trial: Return to work (RTW) for younger stroke survivors in Australia.**

3. Purpose

The 'Return to life, return to work' initiative will fund projects aimed at developing innovative recovery and rehabilitation clinical interventions for younger stroke survivors in Australia - an emerging priority area with unmet needs. These projects will continue to accelerate important neurological research and support Australian researchers to be at the forefront of finding solutions for stroke recovery.

4. Critical dates

Stage	Date
Applications open	**8 October 2018**
Applications close	**5pm AEDT Friday 30 November 2018 (daylight savings time)**
Advice to applicants	**February 2019**

5. Endorsement of Clinical Trials

All clinical trials facilitated by the Stroke Foundation **must** align with Australasian Stroke Trials Network (ASTN) guidelines, and meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA). The data and outcomes collected will be in adherence with the standards set out by the Stroke Recovery and Rehabilitation Roundtable[1].

1 Kwakkel G, et al. Agreed Definitions and a Shared Vision for New Standards in Stroke Recovery Research: The Stroke Recovery and Rehabilitation Roundtable Taskforce. Neurorehabil Neural Repair. 2017;31:793-799

6. Eligibility Criteria

6.1 Clinical Trial: Perispinal Etanercept (PSE) as a therapy promoting recovery after chronic stroke for younger stroke survivors in Australia (particularly those of working age)

A 2.5-year grant of up to $750,000 to support a robust, independent, multi-centred clinical trial of Perispinal Etanercept (PSE) in Australian stroke survivors of working age.

Who may apply?

- Researchers of any career stage may apply.
- The research team must be Australian led.
- International trial sites may be included in the project.
- Lead applicants who have (or have not) previously received a research grant from the Stroke Foundation are eligible.

What may be funded?

- The research plan must follow the specifications detailed in Section 7 application procedure for clinical trials.
- A significant part of the research must be carried out in Australia.
- Preference will be given to those applications including some, or all, of the following criteria:
  i. Have significant community engagement
  ii. Have international collaboration, particularly with funding contribution.
  iii. Applications that follow the CONSORT[2] criteria and TIDieR guidelines[3].
- The grant is to be used for direct research costs such as equipment and, support personnel such as research assistants or casual help, or other assistance necessary for a specific project.

What is not funded?

- This funding does not cover institutional fees; infrastructure costs; overheads; PhD stipends.

2 http://www.consort-statement.org/

3 Better Reporting of Interventions: Template for Intervention Description and Replication (TIDieR) Checklist and Guide Hoffman et al. BMJ 2014

6.2 Clinical Trial: Return to work for younger stroke survivors in Australia.

A 2.5-year grant of up to $250,000 to support a clinical trial of an intervention designed to improve return to work rates for younger stroke survivors in Australia.

Who may apply?

- Researchers of any career stage may apply.
- The research team must be Australian led.
- International trial sites may be included in the project.
- Lead applicants who have (or have not) previously received a research grant from the Stroke Foundation are eligible.

What may be funded?

- The research plan must follow the specifications detailed in Section 7 application procedure for clinical trials.
- A significant part of the research must be carried out in Australia.
- Preference will be given to those applications including some, or all, of the following criteria:
  i. Innovative projects.
  ii. Applications that follow the CONSORT[2] criteria and TIDieR guidelines[3].
- The grant is to be used for equipment, support personnel such as research assistants or casual help, or other assistance necessary for a specific project.

What is not funded?

- The Stroke Foundation does not cover institutional fees; infrastructure costs; overheads; PhD stipends.

7. Application procedure

This Return to work, return to life Clinical Research Grants Application Guide should be read before completing an application form. Application forms are available on the Stroke Foundation website: https://strokefoundation.org.au/clinicaltrials

All applicants are required to use the application template and adhere to length and formatting requirements in the table below and in the application form. Any applications not using the template will be deemed **ineligible**. All details included must be current at the time of the application close date.

Formatting Component	Requirement
File format	PDF
Page size	A4
Page margin	1.7cm left and right margin, 2.5cm top and bottom margin
Page limits	Page limits vary between parts of the application. Refer to the relevant advice and instructions to applicants for applicable page limits.
Font	Arial Size 11
Line spacing	Single

The application form should contain all information necessary for assessment by the review panel, either by reference to published work or by including the essential components as outlined below:

Section	Component	Response Limit	Properties
1.1.	Project Summary	Half page	Outline the research question, methodology and significance of the project
1.4.	Research Team	As required for up to 10 Chief Investigators (CI)	
2.1. - 2.5.	Research Proposal	9 pages	A detailed outline of the research plan that includes: 2.1. Background and Rationale 2.2. Research aims and Hypotheses 2.3. Detailed research plan 2.4. Sample Size Justification and Statistical Analysis 2.5. Project outcomes and Significance
2.6.	Timeline and Milestones	As required for up to 10 milestones, with a heading and two sentence description	There are 6 mandatory milestones provided in the application template. These must be incorporated into the research proposal timeline.
3.1.	CI Track Record including the Top 5 publications in the last 5 years	Up to 2 pages per CI	A track record summary, since 2014, for each Chief Investigator that is relevant to the application and relative to opportunity and career stage. Include details of career

			disruptions in this section. The following areas should be considered: • top 5 publications in the past 5 years relevant to the application • career summary including qualifications, employment and appointment history • research support including grants and fellowships • contribution to field of research which may include the impact of previous research including translation and commercialisation • collaborations • community engagement and participation • professional involvement including committees, conference organisation • international standing including invitations to speak, international committees • supervision and mentoring • peer review involvement including granting organisations, manuscripts, editorial responsibilities • industry relevant expertise and output • other information you think is vital to your application.
3.2.	Publication Track Record for Chief Investigators	Attach as a separate document as required for CIs only, since 2014	Group publications by type (original articles, reviews, editorials, letters to the editor, book chapters, books). Exclude published abstracts from this list.
3.3.	Summary of Team Quality & Capability, including how the team will work together	Up to 1 page	The team must be Australian led, but international investigators may be included in the research team. Their contribution should be highlighted and practicalities of their involvement explained.
4	Project Budget & Justification	As required	Detail for each budget item, on a yearly basis with full justification.
5	References	As required	A full list of references cited in the application.
6	Certifications	1 page	Certification required by the Chief Investigator A (Applicant) and Head of Department in the administering institution/research body.

Research Proposal - 9 pages

Clinical trial proposals must have a research plan that:

- Is well-defined, highly coherent and strongly developed.
- Is based on a clearly defined and robust scientific rationale.

- Has a near flawless study design that is sham-controlled, multi-centred and includes blinding of participants and outcome assessors.
- Has a clearly defined, pre-determined and accepted functional outcome measure, with assessment of neurological recovery by a team independent of the intervention team.
- Has a sample size that is based on quality randomised data that includes feasibility for recruitment timelines.
- Adheres to industry standards including oversight by an independent data safety and monitoring committee that includes membership by neurologists/stroke specialists, rehabilitation/recovery specialists, and a biostatistician.
- Has a registered protocol and statistical analysis plan that is published, prior to unblinding of the data.
- Has a plan for open data access once the study is complete.
- Is highly feasible with all of the required expertise, research tools and techniques established.
- Has all conflicts of interest declared and is independent from the sponsor.
- Has personnel that are all GCP certified (Good Clinical Practice).
- Is highly competitive with the best, similar research proposals internationally.
- Is aimed at a Phase 2b, including a pathway for new indication by the Therapeutic Goods Administration (TGA).
- Has an accepted primary outcome measure in the field of stroke recovery that could theoretically meet TGA approval if confirmed in a large study – provided there was evidence demonstrating the need for a larger study (with the exception of clinical trials that do not involve therapeutic goods).

8. Submission

All applications must be signed and submitted via email to research@strokefoundation.org.au by the closing date and time. Late submissions will not be considered.

Submitted applications will receive a return email acknowledgement from the Stroke Foundation. Please ensure you have received this acknowledgement prior to the deadline.

We understand that situations arise at the last minute that can delay applications. For this reason, we encourage applicants to submit your application at least a day ahead of the deadline. Please be aware that the Stroke Foundation will **not** allow extensions and will **not** allow any applications after the deadline. This includes any IT issues that arise during the submission process. We recommend that you confirm with your research administration office the timing required for certification and the procedure for submission.

Any applications received after the deadline will be deemed ineligible. This ensures an equitable process for all applicants. For queries or to confirm receipt contact research@strokefoundation.org.au or phone Michelle Adamson on (03) 9918 7215.

9. Outcome of application

The Stroke Foundation will advise applicants and their institutional contact via email of the outcome of their submission by February 2019.

10. Approvals to be obtained prior to funding commencing

As per Section 5, the research undertaken must conform to the principles set out by the NHMRC's Statement on Ethical Conduct in Human Research (2007) and The Australian Code for the Responsible Conduct of Research and any other conditions required by Human Research Ethics Committees. The research undertaken must align with Australasian Stroke Trials Network (ASTN) guidelines, and meet the requirements for endorsement by this professional network of stroke specialists under the auspices of the Stroke Society of Australasia (SSA). The data and outcomes collected will be in adherence with the standards set out by the Stroke Recovery and Rehabilitation Roundtable[1].

Funding will not be released to the nominated institution until all relevant approvals, particularly in relation to ethics and governance, have been received and lodged with the Stroke Foundation prior to the commencement of the research.

11. Consumer and community participation

Researchers are encouraged to consider the benefits of actively engaging consumers in their proposed research. Applicants should refer to The Consumer Health Forum of Australia Inc. and NHMRC Statement available at: http://www.nhmrc.gov.au/guidelines/publications/r22-r23-r33-r34

If you would like your research study listed on the Stroke Foundation website to recruit consumers from our community please see:
https://strokefoundation.org.au/What-we-do/Research/Request-for-research-participant-policy

12. Conditions of Research Grant Award

All Research Grants are offered in accordance with the conditions specified in the 'Stroke Foundation Clinical Trials Conditions of Research Grant Award' available on the Stroke Foundation website:
https://strokefoundation.org.au/clinicaltrials

In signing an acceptance of the Clinical Trials Conditions of Research Grant Award, the grant Recipient is agreeing to abide by all the conditions, which includes but is not limited to;

- the research must be undertaken at the nominated institution/s;
- acknowledgement of the Australian Government's support and the Stroke Foundation in agreed format in any presentation or publication of the work;

- annual milestone and financial reporting, and a final report and financial acquittal provided at the end of the grant period;
- agreement that the grant Recipient may be contacted to represent the Stroke Foundation.

13. Varying a grant

Grant Recipients agree to perform the activities specified in the original application. If the Recipient is unable to perform, or to continue to perform, activities in relation to the award, the Stroke Foundation must be notified in writing as soon as practicable.

Variations occur when a grant needs modification from the original proposal submitted. This may include changes in budget or personnel or an amendment to the budget.

Extensions to a research project end date will only be considered in exceptional circumstances, with a maximum extension of 6 months. Requests to amend a grant or the terms and conditions should be made to research@strokefoundation.org.au and a Research Grant Variation Form will be provided.

14. Duration of grant and expenditure of funds

The 'Return to life, return to work' research grants are 2.5 year awards which take effect from the start of the award year (i.e. 1 January 2019 - 30 June 2021).

Funding will be released annually subject to the submission of annual milestone progress and financial reporting, and the Stroke Foundation Clinical Trials Conditions of Research Grant Award. Annual release of funding will be according to the Recipient's yearly budgets as submitted in the application, conditional to:

i. no more than $300,000 budgeted per annum - PSE trial.
ii. no more than $100,000 budgeted per annum - RTW trial.

Annual financial acquittals prepared by the administering institution and in accordance with the yearly budgets submitted are required by 31 December each year of the grant award and at the conclusion of the grant (31 July 2021).

Expenditure of funds must be within the grant period and in accordance with the budget submitted, unless a variation has been approved by the Stroke Foundation. Funds that have not been spent at the conclusion of the award must be returned to the Stroke Foundation within 30 days of the invoice issued to the nominated institution.

15. Reporting

Annual milestone progress reports and financial acquittals are required (31 December each year), and a final report with financial acquittal at the conclusion of the grant (31 July 2021) must be submitted using the templates provided.

Where a grant Recipient fails to submit satisfactory reports when required, the Stroke Foundation may determine that all or part of the funding must be repaid. In addition, a grant Recipient who fails to submit satisfactory reports may not be eligible to apply for future funding rounds of the Stroke Foundation Research Program. All information provided to the Stroke Foundation in progress and final reports may be used for internal reporting, media releases and in any Stroke Foundation publications.

16. Acceptance of grant

Successful applicants and their institutional contact will receive a Letter of Award by email to advise the offer of award. The successful applicant must return written acceptance of the offer of award and the specified documentation by the date nominated within the letter.

17. Review process

The Research Advisory Committee (RAC) oversees the Stroke Foundation Research Program. All applications will be reviewed and ranked by independent and external reviewers. Funding will be awarded to the highest ranking applications. Each funding scheme will be reviewed independently by reviewers allocated to the one scheme.

When reviewing the applications, reviewers are asked to score against each of the criteria outlined in the Descriptors (Descriptors available on the Stroke Foundation website: https://strokefoundation.org.au/clinicaltrials.

Each application is scored with a weighting of 50% for “Research Program” (scientific quality), and 25% for each of “Relevance" to each scheme and “Team Track Record”, by five independent reviewers. The reviewers each receive the same number of applications and, after scoring them, are asked to rank each application. Within each scheme, all of the ranks from all of the reviewers are then combined into one overall ranked list. The RAC is provided with a de-identified copy of these ranked lists. These lists provide a basis for funding recommendations.

18. Timeline of Peer Review Process

Stage	Date
Applications close	**5pm AEDT Friday 30 November 2018**
Applications assigned to external reviewers	December 2018
Grant Review Panel assess and rank applications	January 2019
Funding recommendations prepared	January 2019
RAC meet	February 2019
Advice to applicants	February 2019

19. Enquiries

Any enquiries regarding the administration of grants should be addressed to:
Stroke Foundation: Compliance Officer, Michelle Adamson
Email: research@strokefoundation.org.au
Telephone: 03 9918 7215

Acknowledgement

Funding for this research has been provided by the Medical Research Future Fund (MRFF). The MRFF has been established by the Australian Government to provide grants of financial assistance to support health and medical research and innovation, with the objective of improving the health and wellbeing of Australians. MRFF funding has been provided to Stroke Foundation under the MRFF Accelerated Research Program announced as part the MRFF's disbursement package in October 2018. Further information on the MRFF and disbursements are available at www.health.gov.au/mrff.

We would like to acknowledge Royal Melbourne Hospital Research Directorate for their assistance in providing materials and advice on these documents.

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FAQ's

International

Does the Stroke Foundation award grants internationally?
The research team must be Australian led, but internationally based Investigators and trial sites can be included in the proposal.

Is a project eligible if it is led by Australian researchers but collected data internationally?
Yes, the project could be considered if it also collected data for Australia or would benefit Australian patients.

Can a researcher from another country be the Chief Investigator for the grant, but the research be completed at an Australian University?
People from overseas can be a Chief Investigator, but a significant part of the research must be done in Australia and administered by an Australian institution. The contribution of international Investigators should be highlighted and the practicalities of conducting the study explained.

Grant funds

Are grants subject to the GST of the Stroke Foundation?
Yes.

Does the grant funding cover institutional fees/infrastructure costs/overheads/PhD stipends?
No, the grant funding does not cover any of the above costs.

Can grant funding be used for equipment, research assistant salaries, consumables and travel?
The funding can be for anything that contributes to the study objectives, but the costs must be justified.

Can severance pay be included in grant acquittals?
No. We only include costs that support the actual cost of the project, and so severance pay would not be included.